

**REMARKS**

The application has been carefully reviewed in light of the Office Action dated January 24, 2008. Claims 1-40, 76-79, and 82 are pending. Claims 1, 7, 10, 13, and 15 are amended in this action. Claims 2-6 are canceled without prejudice, waiver, or disclaimer. No new matter is believed to be added by this amendment. In addition, unless a passage of an amendment is specifically discussed below in connection with one or more cited references, Applicants respectfully submit that the remarks accompanying this amendment should be constructed as being submitted merely to clarify the invention rather than as a limitation submitted to overcome a cited reference.

**Claim Rejections under 35 USC §102**

Independent Claims 1 and 21 stand rejected under 35 USC §102 as allegedly being anticipated by Eppstein (6,527,716). Office Action at Para. 2. Applicants respectfully traverse. As amended, independent Claims 1 and 21 read as follows:

1. A method for delivering permeant substances through a biological membrane of an animal comprising applying at least one heated probe element capable of conductively delivering thermal energy via direct contact to the biological membrane to cause the ablation of some portion of the membrane to form a plurality of delivery openings in the membrane, wherein an opening depth of the majority of said delivery openings fall within the range between about 40 and about 90 microns.

21. A method for delivering drugs transdermally into a biological membrane of an animal comprising ablating a plurality of delivery openings through a membrane, wherein said delivery openings have a distribution resulting in a bell-shaped curve with said delivery openings having a mean opening depth of between about 40 and about 90 microns.

Applicants respectfully assert that the cited references fails to anticipate independent Claims 1 or 21, as currently claimed, because differences exist between the claimed invention and the respective disclosure. Particularly, there is no methodology for ablating a plurality of

delivery openings, where a majority of the opening depths of the delivery openings are either between about 40 and about 90 microns or have a distribution resulting in a bell shaped curve with the delivery openings having a mean opening depth of between about 40 and 90 microns disclosed in the references. The Federal Circuit has held that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) (quoting *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771, 218 U.S.P.Q. 781, 789 (Fed. Cir. 1983)) (emphasis in original). See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (“The identical invention must be shown in as complete detail as contained in the . . . claims.”). Clearly there are differences between the apparatus described in cited referenced and the methods as currently claimed in independent Claims 1 and 21.

Nowhere does Eppstein disclose controlling or even measuring the depth of the delivery openings of the micropores. Eppstein discusses a variety of methods for forming micropores, including, but not limited to the use of heat. Eppstein at column 6, lines 6-67. Eppstein also discloses forming micropores with depths that range from 1 micron to 10,000 microns. *Id.* at column 8, lines 15-26. However, Eppstein does not disclose forming a plurality of micropores within a membrane that have delivery opening depths that have a specified depth or a specified depth distribution. As mentioned in the present specification, the size of the delivery opening is critical to the amount of permeant that can be delivered in a given time frame. Therefore, the Applicant respectfully disagrees with the Examiner when he states that, had Eppstein decided to make delivery openings between 40 and 90 microns, the mean opening depth would be between 40 and 90 microns. Office Action at Para. 4. There is simply no disclosure of this assertion in Eppstein.

Therefore, Applicants respectfully request that the Examiner withdraw the Section 102 rejections of pending independent Claims 1 and 21 and those claims that depend therefrom.

**ATTORNEY DOCKET NO. 01107.0019U1**  
**APPLICATION NO. 10/691,968**

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

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A Request for Extension of Time is submitted herewith. Further a fee in the amount of \$60.00 for a one-month extension of time for a small entity is enclosed. Additionally, a Request for Continued Examination is enclosed herewith, with a fee in the amount of \$405.00 for a small entity. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

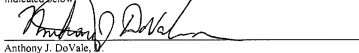


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Anthony J. DeVale, Jr.

5/27/2008  
Date